



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

72

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/789,562

02/27/2004

Artur Mitterer

20695D-000120US

9550

44183

7590

05/17/2006

BAXTER HEALTHCARE CORPORATION  
ONE BAXTER PARKWAY  
MAIL STOP DF2-2E  
DEERFIELD, IL 60015

EXAMINER

ROBINSON, HOPE A

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/789,562

Applicant(s)

MITTERER ET AL.

Examiner

Hope A. Robinson

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 September 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/1/04.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Application Status***

1. Applicant's election with traverse of Group II (claim 17) on March 3, 2006 is acknowledged. Applicant's comments regarding a rejoinder of method claims upon notification of an allowable product is noted.

2. The traversal is on the grounds that all four groups are searched together because applicant argues that they are linked to a single general inventive concept. This argument is germane to lack of unity not restriction practice *per se* as the MPEP in chapter 800 state that restriction requirement is proper if the inventions can be shown to be independent and or distinct. Applicant state the restriction Groups are related as product and process of use. However, as stated in the office action mailed on January 26, 2006, the product can be used in a materially different process and the groups have established a different status in the art, which demonstrates burden of search. Thus, the restriction requirement is deemed proper and is final.

### ***Claim Disposition***

3. Claims 2-16 have been canceled. Claims 1 and 17-22 are pending. Claim 17 is under examination. Claims 1 and 18-22 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

4. The Amendments filed on March 3, 2006 does not have the proper status identifiers for claims 17 and 21. Claim 17 is listed as "new", however, the status identifier should have been "previously presented". Note that claim 21 is listed as "currently amended", yet no indication is made in the claim of what is being changed. As claim 21 is directed to a non-elected claim examination will proceed with the present claim set. The examiner is interpreting this as a typographical error. Clarification of the record is requested.

#### ***Priority***

5. The instant application requests the benefit of priority for the foreign application Austria A 338/97 filed on February 27, 1997 in the declaration. No copy of this foreign document has been received. Without an official, ribboned copy, foreign priority cannot be granted.

The instant application is granted the benefit of priority for U.S. Application No. 09/367,459, filed May 8, 2000.

#### ***Specification***

6. The specification is objected to because of the following informalities:

(a) The specification is objected to because the priority information provided in the amendment filed on February 27, 2004 needs to be updated. Note that Application No. 09/367,459 is now U.S. Patent No. 6,831,159.

(b) The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following is suggested: "Factor VIII/vWF-complex and methods of purifying same".

(c) The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as TRITON® and TWEEN®, for example, have been noted in this application (see pages 15-16). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Correction of the above is required.

### ***Drawing***

7. The drawings are objected to because Figure 1 is dark, thus difficult to discern the lanes. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

Art Unit: 1656

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Information Disclosure Statement***

8. The Information Disclosure Statement filed on June 1, 2004 has been received and entered. The references cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

9. Claim 17 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 17 is drawn to a Factor VIII:C, which reads on a product of nature. The claims should be amended to indicate the hand of

Art Unit: 1656

the inventor, for example the insertion of "isolated" or "purified" in connection with the protein to identify a product not found in nature (see MPEP 2105).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter, which applicant (s) regard as their invention.

Claim 17 is indefinite for the recitation of "substantially free", as it is unclear what amount is considered to be "substantial" and the instant specification does not define the terms. Does this mean 90% free or 95% free?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1656

11. Claim 17 is rejected under 35 U.S.C. 102(b) as being anticipated by SCLAVO (EP 600 480, February 12, 1993).

SCLAVO teach a process that obtains FVIII:C and disclose that there is a need for larger amounts of FVIII concentrates (column 1). SCLAVO teach a purified product following viral inactivation and a cationic exchanger (column 1 and column 4). SCLAVO also teach a sodium chloride concentration of 0.25-0.35M, preferably 0.3M which is equivalent to 250-350mM, preferably 300mM (column 3, second paragraph). Therefore, the limitations of the claim is met by this reference.

### ***Conclusion***

12. No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Patent Examiner

**HOPE A. ROBINSON**  
**PATENT EXAMINER**